Document History

Date	Who and what
9/24/2023	ASH member Dr. Vikas Gupta proposed this guideline topic to the ASH Committee on Quality (COQ).
12/21/2023 to 1/8/2024	The COQ agreed to develop a plan for guidelines on this topic. ASH staff confirmed that the American Society of Clinical Oncology, the British Society of Hematology, and the European Society of Hematology do not have current guidelines or revisions in development on the topic.
2/11 to 2/18/2024	ASH staff Rob Kunkle and Rachel Cohen drafted this plan, incorporating information from the proposal by Dr. Gupta.
2/20/2024	Reviewed by Drs. Adam Cuker and Matthew Cheung. Minor edits. RK and RC added questions to committee and expert reviewers.
2/26/2024	Reviewed by the COQ and the ASH Guideline Oversight Subcommittee. Minor edits by RK.

Plan for New ASH Clinical Practice Guidelines on Myelofibrosis

In 2024, the American Society of Hematology (ASH) will support development of new guidelines on myelofibrosis (MF). This plan describes scope, methods, and timeline.

Background

MF is a rare disease, with an incidence of 0.3-2.0 cases per 100,000 person-years, and prevalence of 0.5-6.0 per 100,000 person years (Shallis et al. 2021). Hematologists and oncologists frequently encounter patients with MF in their clinical practice; however, expertise in the community setting is limited. As a result, patients often receive sub-optimal treatment or delayed referral for transplantation. Since the discovery of the JAK2 mutation, a significant body of literature has emerged about disease biology and about transplant and non-transplant-based therapies for MF. There are several JAK inhibitors (JAKi) approved now, and there is wide variation in selection of treatment options for patients who are eligible for both transplantation and JAKi therapy, criteria used to initiate JAKi therapy and optimal dosage schedule, and management after failure of first-line JAKi therapy.

Several national groups have produced guidelines on MF, including the National Comprehensive Cancer Network (Gerds et al. 2022), the British Society of Hematology (Reilly et al. 2012), and the European Leukemia Network (Barbui et al. 2018). Limitations of these guidelines include outdated evidence reviews or informal methodology and narrow country-specific scope.

Scope and Aims

These guidelines will address 10 clinical questions. Each question will be answered by one or more graded recommendations.

Each question will be formulated in a way that can be answered by a single systematic review of evidence. A standard question will specify a population, a single intervention, and a single comparison. Questions may have multiple comparisons; in this case, each comparison will count as a separate question. For each question, up to 7 outcomes will be analyzed.

The specific questions will be determined by a guideline panel. Potential questions may address the following topics:

Risk stratification

- Which are the optimal tools for risk stratification of MF?
- Should the risk stratification of post-polycythemia vera MF (PPV-MF) or post-essential thrombocythemia MF (PET-MF) be done differently?

Non-transplant therapies

- Should asymptomatic MF patients with intermediate-2 or high-risk disease receive JAKi therapy?
- Should JAKi naïve MF patients with significant anemia or thrombocytopenia be treated differently than those with good marrow reserve?
- What is the optimal management of patients who fail first-line JAKi therapy? (Questions on this topic will include a definition of JAKi therapy failure.)

Transplantation

- What is the optimal timing of transplantation for MF?

These initial guidelines are not expected to be comprehensive, i.e., not all of the above topics are expected to be addressed by questions and recommendations in these initial guidelines. The guideline panel will prioritize questions with greatest potential impact on quality now. After the questions are formulated, ASH will evaluate if an expanded scope is needed. If so, follow-up guideline efforts may be planned, i.e., additional guidelines on additional aspects of iron deficiency not addressed by the initial guidelines.

Available Evidence

A significant body of literature has emerged in the last 15 years to improve risk stratification by integrating histological, cytogenetic and molecular markers with clinical risk factors (Cervantes et al. 2009; Passamonti et al. 2010; Gangat et al. 2011; Guglielmelli et al. 2018; Tefferi et al. 2018). Despite the rarity of the disease, several large randomized clinical trials in JAKi naïve patients (Harrison et al. 2012; Verstovsek et al. 2012; Pardanani et al. 2015; Mesa et al. 2017a; Mesa et al. 2017b) and in JAKi exposed patients (Mascarenhas et al. 2018; Harrison et al. 2018) have been conducted, as well as single arm studies in JAKi exposed patients (Harrison et al. 2017; Gupta et al. 2021). In addition, there are some large observational studies on comparative outcomes of transplant versus non-transplant therapies (Kroger 2012; Gowin et al. 2020; Maze et al. 2020).

Perspective

These new guidelines will provide recommendations for high-resource settings internationally, taking an individual patient perspective (i.e., rather than the perspective of a health system or of policymakers). It is expected that the recommendations may need to be adapted for other settings or perspectives.

Guideline Panel

ASH will form a single guideline panel of 23 individuals, including a clinical co-chair and a methodology co-chair. The panel will mainly include hematologists who are experts in MF, including at least 1 expert

in bone marrow transplant for myelofibrosis. The panel will include 1-2 patient representatives, i.e., individuals with lived experience of the disease, such as a past patient or a caregiver. Ideally, patient representatives will not *also* be physicians. One panelist will be an early career hematologist. At least 1 panelist will represent the perspective of a hematologist who practices in a typical community setting (i.e., not a major research academic setting). One panelist will have expertise in implementation science.

The panel will be diverse with respect to intellectual point of view on the guideline questions, institution, and demographics. Consistent with the goal of developing recommendations for high-resource settings, most or all panelists will be from countries with advanced economies.

Methodology expertise will be provided by the methodology team that supports the panel under a paid agreement with ASH. The principal lead from the methodology team will be invited to serve as the methodology co-chair of the guideline panel.

A member of the ASH Guideline Oversight Subcommittee will serve on the guideline panel as an ex officio member. This individual's role will be to ensure that the guideline development process is conducted in accordance with this project plan and ASH policies and procedures, including ensuring that questions are within scope, reviewing participant disclosures and ensuring adherence to ASH COI policies, and critically reviewing the guideline report for publication.

An early career member of the guideline panel may be asked to serve in a "writer" role. Responsibilities of this role will include drafting background clinical content, recording panel decisions and discussion points, drafting the guideline report, integrating edits by authors into the guideline report, and addressing comments received during public review. At the beginning of the project, panel leadership will discuss and agree with the writer how to appropriately recognize his or her contributions on publication.

At the beginning of the project, panelists with clinical expertise will be designated as primary liaisons and have main responsibility for writing, editing, or reviewing the dissemination and implementation tools described below, e.g., guideline snapshot, teaching slide set, pocket guide, and digital mobile version. At least one panelist will be designated for each tool.

Organizational Collaborators

ASH will not invite other organizations to collaborate in the funding, development, or approval of these guidelines. However, ASH may invite other organizations to recommend experts for the guideline panel, if experts are needed from outside the ASH membership, and to review the guidelines. ASH will also explore with other relevant organizations opportunities to promote and disseminate the guidelines. In addition to endorsement, this could include announcements, summaries, commentaries, or educational programs about the guidelines.

Methods

ASH will contract with a methodology team to support the guideline development process, including to conduct systematic reviews of available evidence, help the guideline panel interpret evidence and form recommendations, and develop a guideline report for publication. The project will require substantial collaboration between the team, the guideline panel, and ASH staff. The specific roles and responsibilities of all participants in the process are described in Appendix A, Roles and Responsibilities.

For the planned scope of these guidelines, expected methodological challenges include a large number of important clinical questions that will require prioritization; a large body of evidence for prognostic risk factors, each of which may require separate systematic review; questions about multiple interventions; and questions for which available evidence may be low certainty.

Through a request for proposal process, ASH will invite methodology teams to propose specific approaches to the above challenges. These specific approaches will be integrated within the following general steps of the ASH guideline development process:

1. ASH forms a guideline panel.
2. The panel prioritizes guideline questions.
3. A methodology team in collaboration with experts on the guideline panel systematically reviews available evidence.
4. The guideline panel reviews and finalizes evidence summaries and forms recommendations.
5. ASH makes the recommendations available for public comment.
6. The guideline panel and the methodology team write a report of the guidelines for publication and dissemination.
7. ASH committees and officers review and approve publication of the guidelines under the imprimatur of ASH.
8. Authors submit the guidelines report to *Blood Advances* for review and publication.

Other general expectations include the following:

The GRADE approach will be used to assess certainty of evidence (Guyatt et al. 2008). The GRADE Evidence-to-Decision framework (Alonso-Coello et al. 2016) will be used to make judgments about the available evidence and form guideline recommendations using standardized language that has well-defined interpretations for clinicians, patients, and policymakers (Izcovich et al. 2020).

Systematic reviews will be conducted according to standards defined by the Cochrane Collaboration or equivalent.

For each guideline question, the best available evidence will be used to make estimates about the health effects of alternative interventions. These estimates, in combination with other judgments, will support recommendations by the guideline panels.

If published direct evidence is not available for a guideline question, the guideline panel may use indirect evidence. For example, if studies are not available showing the effects of an intervention within a prioritized patient population, studies might be found and used that show the effects of the intervention in other, related populations. In this case, the methods team will support the guideline panel to define pragmatic inclusion criteria and methods to identify and use indirect evidence.

If there are no published studies (direct or indirect) to inform a prioritized guideline question, the panel may choose not to answer the question with a recommendation. Alternatively, the panel may base recommendations on unpublished evidence, if the evidence can be systematically collected. For example, unpublished evidence may be collected and synthesized from available registries (Kanter et al. 2021) or from surveys of clinical experts serving on the guideline panel (Mustafa et al. 2021).

In addition to graded recommendations, the guideline panel may offer good practice statements, provided they meet criteria defined by GRADE (Izcovich et al. 2020; Guyatt et al. 2016).

The GRADEPro Guideline Development Tool will be used to summarize evidence, obtain panel voting, and document panel judgments and decisions.

Meetings and Timeline

There will be two in-person meetings of the guideline panel: the first in Q3 2024 to receive orientation and formulate questions, and a second in Q2 2025 to agree on recommendations. Panel meetings will also be held virtually via Zoom. The frequency of virtual meetings will depend on project needs. For some project phases, meetings may occur every other week; for other phases, monthly.

The planned project timeline (approximately 2 years) is as follows:

Step	Total Expected Time (Months)	2024 Q2	Q3	Q4	2025 Q1	Q2	Q3	Q4	2026 Q1
Appoint guideline panel	5	■	■						
Prioritize guideline questions	1		■						
Finalize scope for systematic reviews	1			■					
Conduct systematic reviews	6				■	■			
Develop recommendations	3					■	■		
Public comment	1						■		
Draft guideline report	3-6						■	■	
Organizational review and approval	1							■	
Journal review and publication	TBD								-->

Management of Conflicts of Interest

Conflicts of interest of all participants will be managed in accordance with general ASH policies, as described on the ASH website (https://www.hematology.org/about/governance/conflict-of-interest), and with specific ASH policies and procedures determined by the ASH Guideline Oversight Subcommittee. The most recent version of these policies is attached as Appendix B.

Publication Strategy

Publication strategy for the guidelines and any other intellectual property will be determined by ASH, including the ASH Guideline Oversight Subcommittee. As described in Appendix C, the current strategy is to submit and publish all work relating to this project including the guideline reports and systematic reviews within ASH's online-only open access scientific journal, *Blood Advances*. At the beginning of the project, a presubmission inquiry to the editors of *Blood Advances* will describe all planned work. The inquiry and discussions with the editors will be led by the lead authors and by the GOS ex officio member(s) of the panels.

One guideline report is expected.

Systematic reviews may be developed for submission to *Blood Advances* as separate, simultaneous publications. If the reviews are not prepared as separate publications, details about the reviews will be included with the guideline reports as supplements.

Authorship, sponsorship, and acknowledgements of such publications will be in accordance with academic standards and customs and requirements of the journal of publication. ASH authorship criteria for the guidelines are presented as Appendix D.

Dissemination and Implementation

To support understanding and implementation of the guidelines, the panel will be asked to write recommendations and remarks that are clear and actionable.

As recommendations are drafted, the chair with panelists will develop a dissemination and implementation plan for the guidelines. The plan will identify expected implementation barriers for specific recommendations, e.g., insufficient clinician awareness or insufficient information systems support. Example products that may be developed to address barriers include an informational handout with messaging tailored for clinician, patient, policymaker, and other stakeholders ("snapshot"); a video interview with the chair highlighting key aspects of the guideline; educational teaching slides; a recorded educational webinar; and a digital summary version of the guidelines for the ASH guidelines app. New activities to support the implementation of the guidelines will also be considered, including the development of both clinician and patient-facing decision-making materials.

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